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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,369	11/21/2003	Bruno Simoneau	13/116	3601
28513	7590	08/22/2007		
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,369	<b>Applicant(s)</b> SIMONEAU ET AL.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-16, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 7, 2007.
2. Applicant's election without traverse of invention group IIA, read on claims 17-30 drawn to compounds in which Ar1 is a tetrazole, and the species of compound 504 in the reply filed on June 7, 2007 is acknowledged.

### *Double Patenting Rejections*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 17-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11137831. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds herein claimed and those in '831 are substantially

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overlapped in scope. Particularly, for compounds in '831, Ar may be tetrazole (claim 4), R2 may be halo, alkyl, R4 may be  $-(C=O)NH_2$ , R1 is substituted phenyl, wherein the substituents may include halo, alkyl.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claims Rejections 35 U.S.C. 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girardet et al. (US 2006/0135556).

7. Girardet et al. teach compounds useful as reverse transcriptase inhibitor of HIV, with the structure of HET-L-C(Y)NR<sub>1</sub>R<sub>2</sub>, wherein HET is a 5 or 6 membered heterocyclic ring, preferred heterocyclic ring have at least two of the heteroatoms are nitrogen, and that the two heteroatom are connected to each other, and triazole derivatives are disclosed as examples (0044); L is a linker which may be  $-X-C-$ , wherein X may be S, Y may be oxygen, R<sub>1</sub> is hydrogen or methyl, R<sub>2</sub> may be substituted aryl groups, wherein the substituents may be alkyl, C(O)R', R' is NH<sub>2</sub>. The heterocyclic ring may be substituted with a substituted or unsubstituted aryl group, most preferably, mono-, di-, and tri substituted phenyl, etc., the substituents are selected from lower alkyl, halogen. See, particularly, paragraph 0028-0045, 0047.

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8. Girardet et al. do not teach expressly a compound of the formula HET-L-C(Y)NR<sub>1</sub>R<sub>2</sub>, wherein HET is a tetrazole, or the particular compound elected herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use tetrazole and the HET and make the compound 504 as the compound is within the scope of the disclosure by Girardet et al. Further, Girardet et al. provide sufficient guidance to reach the compound. Particularly, Girardet et al. teach the preferred 5 membered heterocoring comprising at least two nitrogen atoms connected each others and give 1, 2, 4-triazole as example, tetrazole would have been obvious in view of the teaching. As to the 2-chloro, 4-methylphenyl at the tetrazole, note Girardet et al. teaches disubstituted phenyl, wherein the substituent may be lower alkyl and halogen. Regarding the chlorobenzamide, Girardet et al. teach that R<sub>2</sub> may be substituted aryl groups, wherein the substituents may be alkyl, C(O)R', R' is NH<sub>2</sub>. Therefore, the particular compound can be made by following the blue print of Girardet et al. to yield a predictable product, i.e. a reverse transcriptase inhibitor, and would have been obvious to one of ordinary skill in the art. Further, using the compound to make a pharmaceutical composition with proper pharmaceutical excipients would have been within the purview of an ordinary skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang  
Primary Examiner  
Art Unit 1617

S. Shengjun Wang  
PRIMARY EXAMINER